510(k) Summary

MAR 2 8 2013

Proprietary Name:	AxSOS 3 Ti Locking Plate System
Common Name:	Bone plates Bone Screws
Classification Name and Reference:	Single/multiple component metallic bone fixation appliances and accessories 21 CFR §888.3030 Smooth or threaded metallic bone fixation fastener 21 CFR §888.3040
Regulatory Class:	Class II
Product Codes:	87 HRS: Plate, Fixation, Bone 87 HWC : Screw, Fixation, Bone
Sponsor:	Stryker Trauma AG Bohnackerweg 1 CH-2545 Selzach Switzerland
Contact Person:	Estela Celi Regulatory Affairs Specialist 325 Corporate Drive Mahwah, NJ 07430 Phone: (201) 831-6461 Fax: (201) 831-3461 estela.celi@stryker.com
Date Prepared:	December 21, 2012

Description

This Traditional 510(k) submission is being supplied to the U.S. FDA to provide authorization to market the new AxSOS 3 Ti Locking Plate System. The AxSOS 3 Ti Locking Plate System is an internal fixation device that consists of monoaxial plates and various types of screws to fit different types of fractures in the tibia and femur. The subject components will be available sterile and non-sterile. The plates will be available in sizes ranging from 95-415mm in length and the screws will range from 10-150mm in length.

Intended Use
The AxSOS 3 Ti Locking Plate System is intended for long bone fracture fixation.

Indications
The AxSOS 3 Ti Locking Plate System is intended for long bone fracture fixation. Indications include:

- Diapyseal, metaphyseal, epiphyseal, extra- and intra-articular fractures
- Non-unions and malunions
- Normal and osteopenic bone
- Osteotomies

Summary of Technologies
Device comparison showed that the proposed device is substantially equivalent in intended, use, materials and performance characteristics to the following predicate devices:

- K061012/K122308 AxSOS Plus Locking Plate System
- K062564 Synthes LCP Distal Femur Plates
- K052390 Synthes LCP Proximal Tibia Plates
- K972323 Osteo BOS System
- K012162 Stryker Plating System Basic Fragment Set

Non-Clinical Testing
Non-clinical laboratory testing was performed for the AxSOS 3 Ti Locking Plate System components to determine substantial equivalence. Testing demonstrated that the AxSOS 3 Ti Locking Plate System is substantially equivalent to devices currently cleared for marketing.

The following testing was performed:

- Static strength
- Dynamic Fatigue Testing
- Shear-Off Testing
- Insertion Testing
- Pull-Out Testing

Clinical Testing
Clinical testing was not required for this submission.

Conclusion
The AxSOS 3 Ti Locking Plate System is substantially equivalent to the predicate devices identified in this premarket notification.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Stryker Trauma AG
% Ms. Estela Celi
325 Corporate Drive
Mahwah, New Jersey 07430

Letter dated: March 28, 2013

Re: K123964
Trade/Device Name: AxSOS 3 Ti Locking Plate System
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: Class II
Product Code: HRS
Dated: March 6, 2013
Received: March 7, 2013

Dear Ms. Celi:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): _____

Device Name: AxSOS 3 Ti Locking Plate System

Indications for Use:

The AxSOS 3 Ti Locking Plate System is intended for long bone fracture fixation. Indications include:

- Diapyseal, metaphyseal, epiphyseal, extra- and intra-articular fractures
- Non-unions and malunions
- Normal and osteopenic bone
- Osteotomies

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Elizabeth L. Frank -S

Division of Orthopedic Devices